



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|------------------------|---------------------|------------------|
| 10/713,637 | 11/14/2003 | Robert J. Dunki-Jacobs | END-5240 | 2410 |
| 27777 | 7590 | 01/26/2006 | EXAMINER | |
| PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003 | | | JUNG, WILLIAM C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3737 | |

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/713,637 | Applicant(s) DUNKI-JACOBS ET AL. | |
| | Examiner William Jung | Art Unit 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on November 14, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed November 14, 2005 have been fully considered but they are not persuasive.

In regards to claim 12, Kovacs et al disclose that the transponder includes various type of sensor where one of the sensors may be a photosensor to detect changes in an optical property of a dye, a marker or liquid base contrast agent such as Iodine (visible to optical sensor) (col. 1, line 60-65; col. 10, lines 18-27).

In regards to claims 13-18, Kovacs et al 's optical dye disclosed above is not explicitly disclosed as being a particular chemical or biochemical compound. However, the inherency of the composition dye sample to take consideration of either amplifying the tissue of interest by injecting dye solution that has specific chemical or biochemical emission property when excited by illumination. For example, Read et al disclose that the optical dye to target specific tissue includes peptide, monoclonal antibody, genetic materials, etc.

In regards to claims 19-23, Kovacs et al inherently discloses multiple isotope since the spectrophotometer is grated to accommodate multiple wavelength or ranges of wavelength of the radioisotope emission when under excitation.

In regards to claims 1-10, the swallowable subject matter is a merely a method in where the transponder is placed in a patient. More specifically, the acquisition of information along the digestive tract with a capsule such as disclosed by Kovacs et al or Iddan et al can be achieve most efficiently by swallowing the capsule.

Therefore, examiner upholds the previous rejection from Office Action dates June 16, 2005 and repeated below.

2. Applicant's arguments with respect to claim 11 have been considered but are moot in view of the new ground(s) of rejection.

In regard to claim 11, amendment to include limitation swallowable capsule is met by 103(a) with respect to Kovacs et al in view of Iddan et al (see rejection below)

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 12-27 are rejected under 35 U.S.C. 102(b) as being anticipated by *Kovacs et al* (US 5,833,603).

Kovacs et al anticipate all claimed features in claims 11-27.

Claim 12: Kovac et al disclose a system and method for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56)..

Claims 13-18: Kovacs et al further disclose the method above where steps of verifying at least one component and concentration (amount of chemical or biochemical substance) of the physical properties of the tissue, cell, and biochemical components of region of interest.

Although, Kovacs et al do not explicitly state that the detection substance is a monoclonal body,

Art Unit: 3737

peptide, nanoparticle, mRNA and DNS corresponding to a generic monoclonal antibody, and liposome, these are inherent properties of biochemical composition of the tissues and cells (col. 6, lines 26-36).

Claims 19-23: Kovacs et al disclose that the biosensor detects energy spectra via optical or photosensor, which is used along with dye to acquire optical radiation. Although Kovacs et al do not explicitly state use of radioisotopes, the dye solution with radiation optical acquisition is inherent that the dye solution must be radioactive or radioisotopes (col. 1, lines 56-65; col. 4, lines 34-44; col. 5, lines 5-26).

Claims 24-27: Kovacs et al further discloses the method above where the sensor is a spectrophotometer acquiring multiple images of data from a region of interest with predetermine spectrum, wavelengths, and position to detect optical spectrum, i.e. spatial response pattern (col. 1, line 66 – col. 2, line 11).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Kovacs et al* in view of *Iddan et al* (US 5,604,531).

Kovacs et al substantially anticipate all claimed features in claims 1-11. Kovacs et al disclose a system for detecting tissues comprising a capsule comprising a detector, a substance for associating with a target tissue where the substance is capable of being detected by the

Art Unit: 3737

detector and a machine for verifying at least one of the detector and substance are suitable for use (col. 3, line 10 – col. 4, line 59; col. 6, lines 8-56). In addition, Kovacs et al disclose that the capsule includes multiple detectors, a radiation detector, magnetic detector, and single analyzer for each detector (col. 4, lines 35-44). Although Kovacs et al disclose implantation of the sensor device, Kovacs et al do not disclose that the capsule is a swallowable or that the capsule material is coated to allow the capsule to go through the gastro-intestinal (GI) tract. However, Kovacs et al's deficiency is well known in the art where Iddan et al teaches a similar capsule detector where the device is swallowable and coated with material to allow the detector to pass through the GI tract (col. 1, lines 34-40; col. 3, line 8 – col. 5, line 6). Therefore, it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply Kovacs et al's teachings as described above with Iddan et al's device designed to be swallow through the GI tract to achieve the claimed invention.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 3737


however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to William Jung, Ph.D. whose telephone number is 571-272-4739.

The examiner can normally be reached on Mon-Fri 8:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


January 22, 2006


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700